K113614

Roche

FEB 1 2 2013

510(k) Summary

Introduction

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

1) Submitter name, address, contact

Roche Diagnostics Corporation
9115 Hague Rd.
Indianapolis, IN 46250
(317) 521-4793
Contact Person: Nate Carrington
Date Prepared: February 12, 2013

2) Device name

Proprietary names: ACCU-CHEK Compact Plus System
ACCU-CHEK Compact Plus Test Strip
ACCU-CHEK Compact Plus Meter

Classification name: Glucose dehydrogenase, glucose test system (21 C.F.R. § 862.1345)

NBW, Blood Glucose Test System, Over-the-Counter
LFR, Glucose Dehydrogenase

3) Predicate device

ACCU-CHEK Compact System, #k031755

The ACCU-CHEK Compact System is designed to quantitatively measure the concentration of glucose in capillary and venous whole blood. The device is indicated for professional use and over-the-counter sale. The ACCU-CHEK Compact system is indicated for lay person use with capillary whole blood samples drawn from the fingertips, forearm, upper arm, thigh, calf, and palm.

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4) Device Description

The modified test strip is a blood glucose testing product used in conjunction with the ACCU-CHEK® Compact Plus meter.

Through the use of molecular-cloning techniques, Roche has modified the GDH enzyme to improve specificity for glucose; the modified reaction is referred to hereafter as Mut. Q-GDH.

The newly advanced test strip measures blood glucose rapidly and reliably via an electrochemical detection technique. The new version of the test strip employs a disposable dry reagent based on the Mut. Q-GDH method for glucose determination.

When a drop of blood is applied to the test strip first Glucose is oxidized by the enzyme Mut. Q-GDH with simultaneous reduction of the coenzyme. In a second step the coenzyme is reoxidized by the enzyme Mut. Q-GDH with simultaneous reduction of the mediator which finally reduces the indicator chemically to produce the color of heteropolyblue.

5) Intended use

The ACCU-CHEK Compact Plus Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips or palm. The ACCU-CHEK Compact Plus Blood Glucose Monitoring System is intended to be used by a single person and should not be shared.

The ACCU-CHEK Compact Plus Blood Glucose Monitoring System is intended for self- testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. The ACCU-CHEK Compact Plus Blood Glucose Monitoring System should not be used for the diagnosis of or screening of diabetes or for neonatal use. Alternative site testing should be done only during steady - state times (when glucose is not changing rapidly).

The ACCU-CHEK Compact Plus Test Strips are for use with the ACCU-CHEK Compact Plus Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips or palm.

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6) Substantial equivalence	The ACCU-CHEK Compact Plus Test System is substantially equivalent to the ACCU-CHEK Compact System.
7) Data demonstrating substantial equivalence	Performance testing on the ACCU-CHEK Compact Plus System demonstrated that the device meets the performance requirements for its intended use. The data demonstrates that the test strip is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 12, 2013

Roche Diagnostics
c/o Michael Flis
9115 Hague Road
Indianapolis, IN 46250-0457

Re: k113614
Trade/Device Name: ACCU-CHECK Compact Plus Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: II
Product Code: NBW, LFR
Dated: February 05, 2013
Received: February 06, 2013

Dear Mr. Flis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carol C. Benson for

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): k113614

Device Name: ACCU-CHEK Compact Plus Blood Glucose Monitoring System

Indications for Use:

The ACCU-CHEK Compact Plus Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips or palm. The ACCU-CHEK Compact Plus Blood Glucose Monitoring System is intended to be used by a single person and should not be shared.

The ACCU-CHEK Compact Plus Blood Glucose Monitoring System is intended for self- testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. The ACCU-CHEK Compact Plus Blood Glucose Monitoring System should not be used for the diagnosis of or screening of diabetes or for neonatal use. Alternative site testing should be done only during steady - state times (when glucose is not changing rapidly).

The ACCU-CHEK Compact Plus Test Strips are for use with the ACCU-CHEK Compact Plus Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips or palm.

Prescription Use _____ AND/OR Over-The-Counter Use _X_
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Devices and Radiologic Health (OIR)

Katherine Serrano

Division Sign-Off
Office of In Vitro Devices and Radiologic Health

510(k) k113614